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November 21, 2001

VIA FEDERAL EXPRESS

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: **Docket No. 01N-0196 - Supplemental Comments of Novartis Consumer Health, Inc.**

Dear Sir or Madam:

By letter dated October 12, 2001, the Public Citizen Health Research Group ("HRG") objected to comments submitted by Novartis Consumer Health, Inc. ("NCH"), American Home Products Corporation ("AHPC") and Schering-Plough Health Care Products ("Schering") concerning the proposed withdrawal of specified approved new drug applications and abbreviated new drug applications for prescription and over-the-counter drug products containing phenylpropanolamine ("PPA"). By letter dated November 16, 2001, counsel for AHPC made two points in response to HRG's objections: (1) there is no dispute that FDA "should remain neutral in state-law liability matters"; and (2) FDA has "legal authority to advise the world of its neutrality."

As counsel for NCH, we have been authorized to communicate the company's complete endorsement of the two indisputable points made by AHPC. What is distressing about HRG's submission is its misconception of the so-called "disclaimer" that NCH, AHPC and Schering have requested. HRG is under the misimpression that the companies are seeking "some sort of protection . . . from product liability suits"; are trying to "influenc[e] liability determinations in state-law damages actions"; and are attempting to obtain a "substantive" advantage "in product liability litigation." On the contrary, all the so-called disclaimer seeks is a statement of neutrality from FDA in the face of scores of product liability lawsuits across the country invoking FDA's reliance on the HSP findings as proof that the companies have acted in violation of state product-liability laws. In light of this misuse of FDA's reliance, it is only fair and equitable for FDA to state, consistent with its longstanding policy, that its actions do not in any way constitute a determination of state-law liability and are not probative of any of the elements necessary to establish such liability, including prior knowledge of a drug's alleged defects or safety risks. This is all that NCH, AHPC and Schering have asked for. In no way will the requested language shield the companies from liability; it will simply assure that FDA's actions are not improperly weighed in the balance.

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Finally, NCH takes sharp issue with HRG's accusation that NCH falsely represented that "prior to the Yale HSP, there was no scientifically reliable evidence of an association between PPA and hemorrhagic stroke." Try as HRG does to rewrite history, the HSP investigators themselves so stated unambiguously in their own study, as pointed out in NCH's September 12, 2001 comments.

Respectfully submitted,

Randolph S. Sherman

RSS/csb

cc: Christopher FitzPatrick, Esq.
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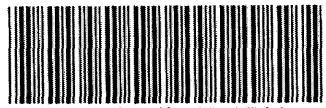

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